Remarks

In response to the Office Action mailed October 23, 2003, Applicants respectfully request reconsideration of the pending claims. To further prosecution of this application, Applicants submit the above amendments and the following remarks. The claims as presented are now in allowable condition.

Claims 1, 2, and 4-27 are currently active in the application. Claim 8 is rejected under 35 U.S.C. §112, claims 1, 2, 4, 5, and 8 rejected under 35 U.S.C. §102(b) as anticipated by Headley et al. (US 5,885,239), and claims 6 and 7 rejected under 35 U.S.C. §103(a) as unpatentable over Headley et al. in view of Lord et al. (US 1,885,457).

Claim 1 has been amended to require a rigid bottom surface spanning the variable volume chamber and substantially flat across the chamber (for support, see application, Figs. 2, 4, 5, and 6), to require an interior wall with at least one hole (for support, see application, page 3, lines 26-27 and Fig. 2), to require a region of convolution separated from the center of the elastic wall by a region without convolution (for support, see application, page 10, lines 2-5 and Figs. 8b and 8c; page 10, lines 15-26 and Figs. 9a and 9b), and to require the region without convolution to be substantially adjacent to the flat bottom surface when in an unstretched state (for support, see application, page 9, lines 27-28). Claim 6 has been amended to require a local maximum in thickness of the diaphragm outside the immediate vicinity of the mounting position (for support, see application, Fig. 7b).

Claims 9-27 have been added. Claims 9 and 10 call for a discrete pocket (for support, see application page 10, lines 20-22 and Fig. 9b) and a chuck accepting a discrete pocket (for support, see application page 10, lines 10-14 and Figs. 9a and 9b).

Claims 11 and 12 call for an asymmetrically convoluted diaphragm and an asymmetric chuck (for support, see application, page 11, lines 1-15). Claims 13-16 call for a rigid bottom surface (for support, see application, page 3, line 28-page 4, line 1), substantially flat (for support, see application, Fig. 2) and formed in part by an interior wall with at least one hole (for support, see application, page 3, lines 26-27). Claims 17-19 call for a groove within the rigid bottom surface that permits fluid to pass to a hole (for support, see application page 4, lines 6-15 and Figs. 4 and 5).

Claim 20 calls for a fluid disposable set including a convolution in a contiguous region of the diaphragm where an unstretched diaphragm departs from the plane of the rigid bottom surface (for support, see application page 9, line 20-page 11, line 15 and Figs. 8a, 8b, 8c, 9a, 9b, 10a, and 10b). Claims 21-22 call for a symmetric convolution distendable into a chuck core (for support, see application page 10, lines 10-26 and Figs. 9a and 9b). Claims 23-25 call for a convolution or convolutions exclusive of a diaphragm axis of rotation distendable into a chuck core (for support, see application page 10, lines 10-26 and Figs. 9a and 9b). Claim 26 calls for discrete chuck core features and convolutions symmetrically positioned about a chuck axis of rotation where the convolutions are distendable into the core features (for support, see application page10, lines 10-26 and Figs. 9a and 9b). Claim 27 calls for discrete chuck core features and convolutions asymmetrically positioned about a chuck axis of rotation where the convolutions are distendable into the core features (for support, see application page 10, line 27-page 11, line 15 and Figs. 10a and 10b).

Compliance with the Written Description Requirement

Claim 1 has been amended to require an interior wall having at least one hole for permitting the passage of fluid therethrough. Figs. 3 and 4 provide support for this amendment in the context of internal wall 237 and holes 239. In view of this amendment, the specification's description of internal wall 237 is consistent with and supports the requirement in claim 1 for an interior wall located within the chamber. (See Office Action, paragraph 2, lines 18-20.)

Also, in contrast with the position of the Office Action, wall 237 provides a flat bottom surface as required by claim 1. (See Office Action, paragraph 2, lines 21-22). The presence of grooves 240 and holes 239 (see Figs. 3 and 4) and holes 30 (see Figs. 1 and 2) does not disqualify use of the descriptor "substantially flat". In each case, the portion of the surface occupied by grooves or holes is much less than the area unoccupied by such features. Indeed, the grooves should be narrow enough so that the diaphragm will not block off flow through the grooves. (See application, page 4, lines 8-15). Consequently, the specification's description of the embodiment is consistent with and supports the requirement of claim 1 for the surface to be "substantially flat". Further, in view of Fig. 4, the flatness of wall 237 extends to rigid wall 10 in forming a flat rigid bottom surface that limits the upward movement of the elastic wall. (See claim 1, element 3). Also, since rigid wall 10 only contributes to the rigid bottom surface in a minor manner, the requirement of substantial flatness is satisfied even if rigid wall were not coplanar with wall 237.

In view of the amendments to claim 1 discussed above, the specification does support claim 8. Consequently, claim 8 now complies with the written description requirement.

Allowability of the Claims Over the Prior Art

Independent claim 1 is directed to a fluid processing disposable set including a fluid port, a variable-volume chamber defined by a rigid wall and an elastic wall, and a substantially flat rigid bottom surface. As amended, the rigid bottom surface "spans the variable volume chamber" and is "substantially flat across the chamber" (claim 1, element 3). (See application, Figs. 2, 4, 5, and 6). The rigid bottom surface includes an interior wall located within the chamber and having "at least one hole for permitting the passage of fluid therethrough" (claim 1, element 3). (See application, page 3, line 27 and related Figs. 1 and 2 for holes 39 in perforate interior wall 40 and page 4, line 12 and related Figs. 3 and 4 for holes 239 in internal wall 237). Also, as amended, the elastic wall is formed by a convoluted diaphragm with a region of convolution "separated from the center of the elastic wall by a region without convolution" (claim 1, element 4; see application, page 10, lines 2-5 and Figs. 8b and 8c; page 10, lines 15-26 and Figs. 9a and 9b) where the region without convolution is "substantially adjacent to the substantially flat rigid bottom surface when in an unstretched state" (claim 1, element 4; see application, page 9, lines 27-28). Since the bottom surface is flat, the convolution of the membrane is not dictated by the shape of the bottom surface.

Independent claim 6 is directed to a fluid processing disposable set including a fluid port, a variable-volume chamber defined by a rigid wall and an elastic wall, and a

rotary seal. A shaped diaphragm forming the elastic wall is essentially planar when unstretched. As amended, the diaphragm varies in thickness "to have a local maximum in thickness outside immediate vicinity of the mounting position" (claim 6, element 3; see application, Fig. 7b).

Headley et al. as Prior Art Distinguished

Headley et al. relate to a method for collecting red blood cells in the space between a perforate interior plate and an elastic impermeable diaphragm where the diaphragm expands to accommodate collection (See Headley et al., Figs. 4 and 12).

Headley et al. lack a region of convolution separated from the center of the elastic wall by a region without convolution as required by claim 1. A convolution is an area of shaped diaphragms where the diaphragms are not planar when in their essentially unstretched position. (See application, page 9, lines 20-22). Examples include dimples (see application, page 10, lines 2-3 and Fig. 8b) and discrete convolutions and pockets (see application, page 10, lines 10-26 and Figs. 9a and 9b). A characteristic of these embodiments is that traverse of the elastic wall from its center to a convolution requires traverse of a section of the elastic wall without a convolution in its unstretched condition. In contrast, elastic diaphragm 31 of the embodiment shown in Fig. 12 of Headley et al. contains a central fold that occupies the center and a region about the center of the diaphragm; traverse from the center requires traverse of a region of convolution.

In addition, the embodiment shown in Fig. 12 of Headley et al. lacks a rigid bottom surface substantially flat across the chamber as required by claim 1. Perforate

interior plate 40 is not flat, as the plate possesses a central region lower than an outer annular region.

Since Headley et al. does not describe a diaphragm with a region of convolution separated from the center of the elastic wall by a region without convolution, and since Fig. 12 of Headley et al. does not show a rigid bottom surface substantially flat across the chamber as required by claim 1, claim 1 is allowable over the cited art and dependent claims 2, 4, 5, and 8 are allowable for at least the same reasons.

Lord et al. as Prior Art Distinguished

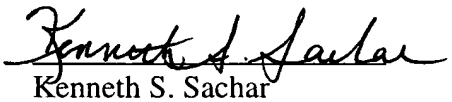
Lord et al. describe a diaphragm mechanism where a rubber diaphragm is secured between plates forming a shell and attached at its center to a central pin. The diaphragm 7 is made thicker near plates 1 and 2 and central pin 9 to reduce the likelihood of separation of the diaphragm from the plates and the central pin. (See Lord et al., page 1, lines 51-52).

Claim 6 as amended requires that the diaphragm have a local maximum in thickness outside of the immediate vicinity of the mounting position. In contrast, Lord et al. specifically provide areas of increased thickness of diaphragm 7 adjacent to mounting positions at the inner periphery (central pin 9) and at the outer periphery (between the seats 14 of plates 1 and 2). The thickness of diaphragm 7 at intermediate points is deliberately made thinner to maintain flexibility. (See Lord et al., page 1, lines 47-50).

Since, Lord et al. teach away from use of a diaphragm with an interior maximum as required by claim 6, claim 6 is allowable over the cited art and dependent claim 7 is allowable for at least the same reasons.

In view of the foregoing amendments and remarks, this application is now in condition for allowance, and a notice to this effect is respectfully requested. If the Examiner believes, after these amendments, that the application is not in condition for allowance, the Examiner is invited to call the Applicants' attorney at the number listed below.

Respectfully submitted,



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